CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

207968Orig1s000

ADMINISTRATIVE and CORRESPONDENCE DOCUMENTS

ACTION PACKAGE CHECKLIST

APPLICATION INFORMATION[1]

NDA # **207968** BLA #	NDA Supplement # BLA Supplement #	If NDA, Efficacy Supplement Type: *(an action package is not required for SE8 or SE9 supplements)*
Proprietary Name: **Jadenu® Sprinkle** Established/Proper Name: **deferasirox** Dosage Form: granules		Applicant: **Novartis Pharmaceuticals Corporation** Agent for Applicant (if applicable):
RPM: **Suria Yesmin**		Division: **Division of Hematology Products**

NDA Application Type: ☒ 505(b)(1) ☐ 505(b)(2)
Efficacy Supplement: ☐ 505(b)(1) ☐ 505(b)(2)

BLA Application Type: ☐ 351(k) ☐ 351(a)
Efficacy Supplement: ☐ 351(k) ☐ 351(a)

For ALL 505(b)(2) applications, two months prior to EVERY action:

- **Review the information in the 505(b)(2) Assessment and submit the draft[2] to CDER OND IO for clearance.**
- **Check Orange Book for newly listed patents and/or exclusivity (including pediatric exclusivity)**

☐ No changes
☐ New patent/exclusivity *(notify CDER OND IO)*
Date of check:

Note: If pediatric exclusivity has been granted or the pediatric information in the labeling of the listed drug changed, determine whether pediatric information needs to be added to or deleted from the labeling of this drug.

❖ Actions	
• Proposed action • User Fee Goal Date is 05/21/2017	☒ AP ☐ TA ☐ CR
• Previous actions *(specify type and date for each action taken)*	☒ None
❖ If accelerated approval or approval based on efficacy studies in animals, were promotional materials received? Note: Promotional materials to be used within 120 days after approval must have been submitted (for exceptions, see http://www fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm069965.pdf). If not submitted, explain _____	☐ Received
❖ Application Characteristics[3]	

[1] The **Application Information** Section is (only) a checklist. The **Contents of Action Package** Section (beginning on page 2) lists the documents to be included in the Action Package.
[2] For resubmissions, 505(b)(2) applications must be cleared before the action, but it is not necessary to resubmit the draft 505(b)(2) Assessment to CDER OND IO unless the Assessment has been substantively revised (e.g., new listed drug, patent certification revised).
[3] Answer all questions in all sections in relation to the pending application, i.e., if the pending application is an NDA or BLA supplement, then the questions should be answered in relation to that supplement, not in relation to the original NDA or BLA.

Review priority: ☒ Standard ☐ Priority
Chemical classification (new NDAs only): Type 5 – New Formulation or New Manufacturer
(confirm chemical classification at time of approval)

☐ Fast Track
☐ Rolling Review
☒ Orphan drug designation
☐ Breakthrough Therapy designation
☐ Rx-to-OTC full switch
☐ Rx-to-OTC partial switch
☐ Direct-to-OTC

(NOTE: Set the submission property in DARRTS and notify the CDER Breakthrough Therapy Program Manager;
Refer to the "RPM BT Checklist for Considerations after Designation Granted" for other required actions: CST SharePoint)

NDAs: Subpart H
☐ Accelerated approval (21 CFR 314.510)
☐ Restricted distribution (21 CFR 314.520)
Subpart I
☐ Approval based on animal studies

BLAs: Subpart E
☐ Accelerated approval (21 CFR 601.41)
☐ Restricted distribution (21 CFR 601.42)
Subpart H
☐ Approval based on animal studies

☐ Submitted in response to a PMR
☐ Submitted in response to a PMC
☐ Submitted in response to a Pediatric Written Request

REMS: ☐ MedGuide
☐ Communication Plan
☐ ETASU
☐ MedGuide w/o REMS
☐ REMS not required

Comments:

❖ BLAs only: Is the product subject to official FDA lot release per 21 CFR 610.2 *(approvals only)*	☐ Yes ☐ No
❖ Public communications *(approvals only)*	
• Office of Executive Programs (OEP) liaison has been notified of action	☐ Yes ☒ No
• Indicate what types (if any) of information were issued	☒ None ☐ FDA Press Release ☐ FDA Talk Paper ☐ CDER Q&As ☐ Other
❖ Exclusivity	
• Is approval of this application blocked by any type of exclusivity (orphan, 5-year NCE, 3-year, pediatric exclusivity)? • If so, specify the type	☒ No ☐ Yes
❖ Patent Information (NDAs only)	
• Patent Information: Verify that form FDA-3542a was submitted for patents that claim the drug for which approval is sought.	☒ Verified ☐ Not applicable because drug is an old antibiotic.

CONTENTS OF ACTION PACKAGE

Officer/Employee List

❖ List of officers/employees who participated in the decision to approve this application and consented to be identified on this list *(approvals only)*	☒ Included
Documentation of consent/non-consent by officers/employees	☒ Included

Action Letters	
❖ Copies of all action letters *(including approval letter with final labeling)*	Approval 05/18/2017
Labeling	
❖ Package Insert *(write submission/communication date at upper right of first page of PI)*	
• Most recent draft labeling *(if it is division-proposed labeling, it should be in track-changes format)*	☐ Included
• Original applicant-proposed labeling	☒ Included
❖ Medication Guide/Patient Package Insert/Instructions for Use/Device Labeling *(write submission/communication date at upper right of first page of each piece)*	☐ Medication Guide ☐ Patient Package Insert ☐ Instructions for Use ☐ Device Labeling ☐ None
• Most-recent draft labeling *(if it is division-proposed labeling, it should be in track-changes format)*	☐ Included
• Original applicant-proposed labeling	☐ Included
❖ Labels (**full color** carton and immediate-container labels) *(write submission/communication date on upper right of first page of each submission)*	
• Most-recent draft labeling	☒ Included
❖ Proprietary Name • Acceptability/non-acceptability letter(s) *(indicate date(s))* • Review(s) *(indicate date(s)*	**Letter 11/22/2016** **Review 11/22/2016**
❖ Labeling reviews *(indicate dates of reviews)*	RPM: **09/28/2016** DMEPA: **02/22/2017** DMPP/PLT (DRISK): ☒ None OPDP: **03/08/2017** SEALD: ☒ None CSS: ☒ None Product Quality: ☒ None Other: ☒ None
Administrative / Regulatory Documents	
❖ RPM Filing Review[4]/Memo of Filing Meeting *(indicate date of each review)* ❖ All NDA 505(b)(2) Actions: Date each action cleared by 505(b)(2) Clearance Committee	**09/19/2016** ☐ Not a (b)(2)
❖ NDAs/NDA supplements only: Exclusivity Summary *(signed by Division Director)*	☒ Completed
❖ Application Integrity Policy (AIP) Status and Related Documents http://www fda.gov/ICECI/EnforcementActions/ApplicationIntegrityPolicy/default.htm	
• Applicant is on the AIP	☐ Yes ☒ No

[4] Filing reviews for scientific disciplines are NOT required to be included in the action package.

• This application is on the AIP ○ If yes, Center Director's Exception for Review memo *(indicate date)* ○ If yes, OC clearance for approval *(indicate date of clearance communication)*	☐ Yes ☒ No ☐ Not an AP action
❖ Pediatrics *(approvals only)* • Date reviewed by PeRC _____ If PeRC review not necessary, explain: Has orphan designation	
❖ Breakthrough Therapy Designation	☒ N/A
• Breakthrough Therapy Designation Letter(s) (granted, denied, an/or rescinded)	
• CDER Medical Policy Council Breakthrough Therapy Designation Determination Review Template(s) *(include only the completed template(s) and not the meeting minutes)*	
• CDER Medical Policy Council Brief – Evaluating a Breakthrough Therapy Designation for Rescission Template(s) *(include only the completed template(s) and not the meeting minutes)* *(completed CDER MPC templates can be found in DARRTS as clinical reviews or on the MPC SharePoint Site)*	
❖ Outgoing communications: letters, emails, and faxes considered important to include in the action package by the reviewing office/division (e.g., clinical SPA letters, RTF letter, Formal Dispute Resolution Request decisional letters, etc.) *(do not include OPDP letters regarding pre-launch promotional materials as these are non-disclosable; do not include Master File letters; do not include previous action letters, as these are located elsewhere in package)*	**05/12/17; 05/01/2017; 03/14/2017; 02/22/2017; 12/19/2016; 12/14/2016; 12/09/2016; 11/07/2016; 10/04/2016; 09/30/2016; 09/26/2016; 09/13/2016; 08/22/2016; 08/08/2016**
❖ Internal documents: memoranda, telecons, emails, and other documents considered important to include in the action package by the reviewing office/division (e.g., Regulatory Briefing minutes, Medical Policy Council meeting minutes)	**N/A**
❖ Minutes of Meetings	
• If not the first review cycle, any end-of-review meeting *(indicate date of mtg)*	☒ N/A or no mtg
• Pre-NDA/BLA meeting *(indicate date of mtg)*	☒ No mtg
• EOP2 meeting *(indicate date of mtg)*	☒ No mtg
• Mid-cycle Communication *(indicate date of mtg)*	☒ N/A
• Late-cycle Meeting *(indicate date of mtg)*	☒ N/A
• Other milestone meetings (e.g., EOP2a, CMC focused milestone meetings) *(indicate dates of mtgs)*	
❖ Advisory Committee Meeting(s)	☒ No AC meeting
• Date(s) of Meeting(s)	
Decisional and Summary Memos	
❖ Office Director Decisional Memo *(indicate date for each review)*	☒ None
Division Director Summary Review *(indicate date for each review)*	☐ None 05/17/17
Cross-Discipline Team Leader Review *(indicate date for each review)*	☒ None 05/16/17
PMR/PMC Development Templates *(indicate total number)*	☒ None

Clinical	
❖ Clinical Reviews	
• Clinical Team Leader Review(s) *(indicate date for each review)*	☒ No separate review **Cosigned 05/01/2017 review**
• Clinical review(s) *(indicate date for each review)*	**05/01/2017**
• Social scientist review(s) (if OTC drug) *(indicate date for each review)*	☒ None
❖ Financial Disclosure reviews(s) or location/date if addressed in another review OR If no financial disclosure information was required, check here ☐ and include a review/memo explaining why not *(indicate date of review/memo)*	**See page 14 of the clinical review dated 05/01/2017**
❖ Clinical reviews from immunology and other clinical areas/divisions/Centers *(indicate date of each review)*[5]	☒ None
❖ Controlled Substance Staff review(s) and Scheduling Recommendation *(indicate date of each review)*	☒ N/A
❖ Risk Management • REMS Documents and REMS Supporting Document *(indicate date(s) of submission(s))* • REMS Memo(s) and letter(s) *(indicate date(s))* • Risk management review(s) and recommendations (including those by OSE and CSS) *(indicate date of each review and indicate location/date if incorporated into another review)*	☒ None
❖ OSI Clinical Inspection Review Summary(ies) *(include copies of OSI letters to investigators)*	☒ None requested
Clinical Microbiology ☒ None	
❖ Clinical Microbiology Team Leader Review(s) *(indicate date for each review)*	☐ No separate review
Clinical Microbiology Review(s) *(indicate date for each review)*	☐ None
Biostatistics ☒ None	
❖ Statistical Division Director Review(s) *(indicate date for each review)*	☐ No separate review
Statistical Team Leader Review(s) *(indicate date for each review)*	☐ No separate review
Statistical Review(s) *(indicate date for each review)*	☐ None
Clinical Pharmacology ☐ None	
❖ Clinical Pharmacology Division Director Review(s) *(indicate date for each review)*	☐ No separate review
Clinical Pharmacology Team Leader Review(s) *(indicate date for each review)*	☒ No separate review **Cosigned 04/13/2017 review**
Clinical Pharmacology review(s) *(indicate date for each review)*	**04/13/2017**
❖ OSI Clinical Pharmacology Inspection Review Summary *(include copies of OSI letters)*	**04/14/2017; 02/17/2017**

[5] For Part 3 combination products, all reviews from the reviewing Center(s) should be entered into the official archive (for further instructions, see "Section 508 Compliant Documents: Process for Regulatory Project Managers" located in the CST electronic repository).

Nonclinical ☐ None	
❖ Pharmacology/Toxicology Discipline Reviews	
• ADP/T Review(s) *(indicate date for each review)*	☐ No separate review
• Supervisory Review(s) *(indicate date for each review)*	☒ No separate review **Cosigned 05/02/2017 review**
• Pharm/tox review(s), including referenced IND reviews *(indicate date for each review)*	**05/02/2017**
❖ Review(s) by other disciplines/divisions/Centers requested by P/T reviewer *(indicate date for each review)*	☒ None
❖ Statistical review(s) of carcinogenicity studies *(indicate date for each review)*	☒ No
❖ ECAC/CAC report/memo of meeting	☒ None Included in P/T review, page
❖ OSI Nonclinical Inspection Review Summary *(include copies of OSI letters)*	☒ None requested
Product Quality ☐ None	
❖ Product Quality Discipline Reviews[6]	
• Tertiary review (*indicate date for each review*)	☒ None
• Secondary review (e.g., Branch Chief) *(indicate date for each review)*	☒ None
• Integrated Quality Assessment (contains the Executive Summary and the primary reviews from each product quality review discipline) *(indicate date for each review)*	**04/19/2017**
❖ Reviews by other disciplines/divisions/Centers requested by product quality review team *(indicate date of each review)*	☒ None
❖ Environmental Assessment (check one) (original and supplemental applications)	
☒ Categorical Exclusion *(indicate review date)(all original applications and all efficacy supplements that could increase the patient population)*	**See page 3 of the Executive Summary in the Integrated Quality Assessment review dated 04/19/2017**
☐ Review & FONSI *(indicate date of review)*	
☐ Review & Environmental Impact Statement *(indicate date of each review)*	
❖ Facilities Review/Inspection	
☒ Facilities inspections (indicate date of recommendation; within one week of taking an approval action, confirm that there is an acceptable recommendation) *(only original applications and efficacy supplements that require a manufacturing facility inspection(e.g., new strength, manufacturing process, or manufacturing site change)*	☒ Acceptable Re-evaluation date: ☐ Withhold recommendation ☐ Not applicable

[6] Do not include Master File (MF) reviews or communications to MF holders. However, these documents should be made available upon signatory request.

Day of Approval Activities	
❖ For all 505(b)(2) applications: • Check Orange Book for newly listed patents and/or exclusivity (including pediatric exclusivity)	☐ No changes ☐ New patent/exclusivity *(Notify CDER OND IO)*
• Finalize 505(b)(2) assessment	☐ Done
❖ For Breakthrough Therapy (BT) Designated drugs: • Notify the CDER BT Program Manager	☐ Done *(Send email to CDER OND IO)*
❖ For products that need to be added to the flush list (generally opioids): Flush List • Notify the Division of Online Communications, Office of Communications	☐ Done
❖ Send a courtesy copy of approval letter and all attachments to applicant by fax or secure email	☒ Done
❖ If an FDA communication will issue, notify Press Office of approval action after confirming that applicant received courtesy copy of approval letter	☐ Done
❖ Ensure that proprietary name, if any, and established name are listed in the *Application Product Names* section of DARRTS, and that the proprietary name is identified as the "preferred" name	☒ Done
❖ Ensure Pediatric Record is accurate	☐ Done
❖ Send approval email within one business day to CDER-APPROVALS	☒ Done

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/s/

SURIA YESMIN
05/19/2017

From: Yesmin, Suria
To: Mancini, Rebecca
Cc: Yesmin, Suria; Baird, Amy
Subject: NDA 207968 Jadenu Sprinkle/Revised FDA Proposed Labeling/Due 05.15.17
Date: Friday, May 12, 2017 11:59:01 AM
Attachments: NDA 207968_revised USPI_05122017.doc

Dear

Please see attached the revised draft of the PI for NDA 207968, Jadenu Sprinkle. Please review the Agency's changes/comments and do the following to the same drafts:

- Accept all changes that you agree with
- Edit over the ones that you do not agree with (do not reject any changes that the FDA proposed)
- Make revisions requested in the comments section

After you have made the changes, please send me the final clean word version of the document. Also, please submit the final agreed-upon label to the NDA.

Please respond by **Monday, May 15, 2017**.

Please confirm receipt.

Thank you,
Suria

Suria Yesmin
Regulatory Project Manager
Division of Hematology Products (DHP)
FDA/CDER/OHOP
WO22, Room 3224
10903 New Hampshire Avenue
Silver Spring, MD 20993
Phone: 301-348-1725
E-Mail: Suria.Yesmin@fda.hhs.gov

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/s/

SURIA YESMIN
05/12/2017

From:	Yesmin, Suria
To:	Mancini, Rebecca
Cc:	Yesmin, Suria; Baird, Amy
Subject:	NDA 207968 Jadenu Sprinkle/Revised FDA Proposed Labeling/Due 05.04.17
Date:	Monday, May 01, 2017 1:24:25 PM
Attachments:	NDA 207968_draft label_changes_21Mar2017_NovartisResponse_FINAL_Formatted.doc

Dear Rebecca,

Please see attached the revised draft of the PI for NDA 207968, Jadenu Sprinkle. Please review the Agency's changes/comments and do the following to the same drafts:

- Accept all changes that you agree with
- Edit over the ones that you do not agree with (do not reject any changes that the FDA proposed)
- Make revisions requested in the comments section

After you have made the changes, please send me the revised tracked changes documents (Word version). Any edits you make should be in tracked changes.

Please respond by **Thursday, May 4, 2017**.

Please confirm receipt.

Thank you,
Suria

Suria Yesmin
Regulatory Project Manager
Division of Hematology Products (DHP)
FDA/CDER/OHOP
WO22, Room 3224
10903 New Hampshire Avenue
Silver Spring, MD 20993
Phone: 301-348-1725
E-Mail: Suria.Yesmin@fda.hhs.gov

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/s/

SURIA YESMIN
05/01/2017

From:	Yesmin, Suria
To:	Mancini, Rebecca
Cc:	Baird, Amy; Yesmin, Suria
Subject:	NDA 207968 Jadenu Sprinkle/Revised FDA Proposed Labeling/Due 03.21.17
Date:	Tuesday, March 14, 2017 12:01:34 PM
Attachments:	NDA 207968_draft label_changes_02Mar2017_NovartisResponse_Final_030917.doc

Dear Rebecca,

Please see attached the revised draft of the PI for NDA 207968, Jadenu Sprinkle. Please review the Agency's changes/comments and do the following to the same drafts:

- Accept all changes that you agree with
- Edit over the ones that you do not agree with (do not reject any changes that the FDA proposed)
- Make revisions requested in the comments section

After you have made the changes, please send me the revised tracked changes documents (Word version). Any edits you make should be in tracked changes.

Please respond by **Tuesday, March 21, 2017, at 4pm EST**.

Please confirm receipt.

Thank you,
Suria

Suria Yesmin
Regulatory Project Manager
Division of Hematology Products (DHP)
FDA/CDER/OHOP
WO22, Room 3224
10903 New Hampshire Avenue
Silver Spring, MD 20993
Phone: 301-348-1725
E-Mail: Suria.Yesmin@fda.hhs.gov

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/s/

SURIA YESMIN
03/14/2017

From:	Yesmin, Suria
To:	Mancini, Rebecca
Cc:	Baird, Amy; Yesmin, Suria
Subject:	NDA 207968 Jadenu Sprinkle/FDA Proposed Labeling/Due 03.02.17
Date:	Wednesday, February 22, 2017 2:52:52 PM
Attachments:	NDA 207968_proposed Label_track changes_022217.doc

Dear Rebecca,

Please see attached revised draft of the PI for NDA 207968, Jadenu Sprinkle. Please review the Agency's changes/comments and do the following to the same draft:

- Accept all changes that you agree with
- Edit over the ones that you do not agree with (do not reject any changes that the FDA proposed)
- Make revisions requested in the comments section

Please note additional edit maybe forthcoming as this is not the final labeling.

After you have made the changes, please send me the revised tracked changes documents (Word version). Any edits you make should be in tracked changes.

Please provide the labeling to me via email by **Thursday, March 2, 2017, at 12pm EST**.

Please confirm receipt.

Kind regards,
Suria

Suria Yesmin
Regulatory Project Manager
Division of Hematology Products (DHP)
FDA/CDER/OHOP
WO22, Room 3224
10903 New Hampshire Avenue
Silver Spring, MD 20993
Phone: 301-348-1725
E-Mail: Suria.Yesmin@fda.hhs.gov

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/s/

SURIA YESMIN
02/22/2017

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 207968

INFORMATION REQUEST

Novartis Pharmaceuticals Corporation
Attention: Haifeng Wu
Associate Director, Global Regulatory CMC
One Health Plaza, Building 339/01/1190
East Hanover, NJ 07936-1080

Dear Mr. Wu:

Please refer to your New Drug Application (NDA) submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Jadenu ® Sprinkle (deferasirox) granules 90mg, 180mg, and 360mg.

We also refer to your July 21, 2016 submission, containing your new drug application.

We are reviewing the Chemistry, Manufacturing, and Controls sections of your submission and have the following comments and information requests. We request a prompt written response in order to continue our evaluation of your NDA.

Drug Product:

1) Clarify whether the drug substance undergoes physical changes during manufacturing and stability of the drug product. If there is a change, provide the control strategy for potential polymorphic changes of the drug substance in the drug product during manufacturing and stability.
2) Discuss the impact of particle size of drug substance, excipients and granules on critical quality attributes with data. If there is an impact adopt a control strategy for particle size variations.
3) Discuss the potential changes of palatability (due to lack of taste masking) attribute after reconstitution in soft food and its impact on patient acceptance. If there is an adverse impact, discuss your strategies for patient compliance for the dosing regimen.
4) Provide a justified sampling plan with statistical validity for each of analytical test methods for the drug product.

5) Adopt specification for water content; otherwise, justify.
6) Adopt a specification for elemental impurities as recommended in the ICH "Q3D Elemental Impurities Guidance for Industry".
7) Include theoretical plate count and capacity factor as a part of system suitability test for HPLC assay method for dissolution samples, uniformity of delivered dose, and assay, degradation products, and identity.
8) Provide USP <661> and USP <671> test results applicable for the sachet including moisture vapor transmission rates. Alternatively, you may reference the DMF with specific submission dates for these information. Also, include a typical certificate of analysis of the sachet.
9) Adopt a seal integrity test for the finished drug product, as a part of process control or drug product specification. Include the test method.
10) Provide your acceptance criteria for bulk packaging components and include CFR citation for food contact for individual components, if a bulk package is used prior to filling the granules in sachets.
11) The proprietary name of the drug product is "Jadenu Sprinkle" and not "Jadenu". Therefore, make changes to the PI to reflect the correct proprietary name. For example the paragraph in the "Description" section should read as: "JADENU Sprinkle (deferasirox) granules contain---poloxamer (188)" (b) (4) (b) (4).
12) In the container and carton label, change the following statement from (b) (4) (b) (4) to: "each sachet contains 162 mg granule equivalent to 90 mg deferasirox". Similar comments apply to sachets for other strengths.
13) List the inactive ingredients by their established name on the carton label.

If you have any questions, please contact me, at (240) 402-6153. Please respond by January 15, 2017.

Sincerely,

Rabiya Laiq, Pharm.D.
Regulatory Business Process Manager
Office of Program and Regulatory Operations
Office of Pharmaceutical Quality
Center for Drug Evaluation and Research

Rabiya Laiq -S

Digitally signed by Rabiya Laiq -S
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, cn=Rabiya Laiq -S, 0.9.2342.19200300.100.1.1=2001555007
Date: 2016.12.19 19:36:17 -05'00'

From:	Kallungal, Beatrice
To:	sara.lorie@novartis.com; shanthi.ganeshan@novartis.com; rebecca.mancini@novartis.com
Cc:	Yesmin, Suria; Kallungal, Beatrice; Baird, Amy
Subject:	NDA 207968, JADENU Sprinkle (deferasirox) - Information request - 12/14/2016
Date:	Wednesday, December 14, 2016 4:07:29 PM

Hello,
Please find the enclosed information request for NDA 207968, JADENU Sprinkle (deferasirox). Please submit your response to this request via e-mail **by 11 AM EST tomorrow, December 15, 2016**. Also please officially submit your response to the NDA.

> *In reference to the two DMPK dog studies (1.Study # dmpk-r1000323 and 2.Study # dmpk-r0900739), please clarify which formulation given to dogs is most similar to the New formulation JADENU® Sprinkle (deferasirox) granules.*

Please acknowledge receipt of this request.

Thanks,

(For Suria Yesmin)

Beatrice Kallungal
Senior Regulatory Health Project Manager
Division of Hematology Products (DHP)
FDA/CDER/OHOP
WO22, Room 2354
10903 New Hampshire Avenue
Silver Spring, MD 20993
(301) 796-9304 (phone)
(301) 796-9845 (fax)
E-Mail: beatrice.kallungal@fda.hhs.gov

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

BEATRICE A KALLUNGAL
12/14/2016

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 207968

INFORMATION REQUEST

Novartis Pharmaceuticals Corporation
Attention: Haifeng Wu
Associate Director, Global Regulatory CMC
One Health Plaza, Building 339/01/1190
East Hanover, NJ 07936-1080

Dear Mr. Wu:

Please refer to your New Drug Application (NDA) submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Jadenu ® Sprinkle (deferasirox) granules 90mg, 180mg, and 360mg.

We also refer to your July 21, 2016 submission, containing your new drug application.

We are reviewing the Chemistry, Manufacturing, and Controls sections of your submission and have the following comments and information requests. We request a prompt written response in order to continue our evaluation of your NDA.

Drug Process:

1) Your evaluation of risk to the sachet filling process [redacted] to be investigated. You did not discuss [redacted] Please discuss the risk [redacted] on sachet fill weight variation during your sachet filling process.
2) We acknowledge your statistical evaluation of the filling process indicates your process is capable of meeting the in-process controls for individual fill weights. Please discuss [redacted]

If you have any questions, please contact me, at (240) 402-6153. Please respond by **January 9, 2017.**

Sincerely,

Rabiya Laiq, Pharm.D.
Regulatory Business Process Manager
Office of Program and Regulatory Operations
Office of Pharmaceutical Quality
Center for Drug Evaluation and Research

Rabiya Laiq -S

Digitally signed by Rabiya Laiq -S
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, cn=Rabiya Laiq -S, 0.9.2342.19200300.100.1.1=2001555007
Date: 2016.12.09 12:49:24 -05'00'

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 207968

PROPRIETARY NAME REQUEST
CONDITIONALLY ACCEPTABLE

Novartis Pharmaceuticals Corporation
One Health Plaza
East Hanover, New Jersey 07936

ATTENTION: Sara Lorie, MBA
Senior Associate Director, Regulatory Affairs

Dear Ms. Lorie:

Please refer to your New Drug Application (NDA) dated and received July 21, 2016, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Deferasirox Granules, 90 mg, 180 mg, and 360 mg.

We also refer to your correspondence, dated and received September 13, 2016, requesting review of your proposed proprietary name, Jadenu Sprinkle.

We have completed our review of the proposed proprietary name, Jadenu Sprinkle and have concluded that it is conditionally acceptable.

If any of the proposed product characteristics as stated in your September 13, 2016, submission are altered prior to approval of the marketing application, the proprietary name should be resubmitted for review. Additionally, if your application receives a complete response, a new request for name review for your proposed name should be submitted when you respond to the application deficiencies.

If you require information on submitting requests for proprietary name review or PDUFA performance goals associated with proprietary name reviews, we refer you to the following:

- Guidance for Industry Contents of a Complete Submission for the Evaluation of Proprietary Names (http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM075068.pdf)
- PDUFA Reauthorization Performance Goals and Procedures Fiscal Years 2013 through 2017, (http://www.fda.gov/downloads/ForIndustry/UserFees/PrescriptionDrugUserFee/UCM270412.pdf)

If you have any questions regarding the contents of this letter or any other aspects of the proprietary name review process, contact Sarah Harris, Safety Regulatory Project Manager in the Office of Surveillance and Epidemiology at (240) 402-4774. For any other information regarding this application, contact Suria Yesmin, Regulatory Project Manager, in the Office of New Drugs at (301) 348-1725.

Sincerely,

{See appended electronic signature page}

Todd Bridges, RPh
Director
Division of Medication Error Prevention and Analysis
Office of Medication Error Prevention and Risk Management
Office of Surveillance and Epidemiology
Center for Drug Evaluation and Research

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

LOUIS R FLOWERS
11/22/2016

LUBNA A MERCHANT on behalf of TODD D BRIDGES
11/22/2016

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 207968

INFORMATION REQUEST

Novartis Pharmaceuticals Corporation
Attention: Haifeng Wu
Associate Director, Global Regulatory CMC
One Health Plaza, Building 339/01/1190
East Hanover, NJ 07936-1080

Dear Mr. Wu:

Please refer to your New Drug Application (NDA) submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Jadenu ® Sprinkle (deferasirox) granules 90mg, 180mg, and 360mg.

We also refer to your July 21, 2016 submission, containing your new drug application.

We are reviewing the Chemistry, Manufacturing, and Controls sections of your submission and have the following comments and information requests. We request a prompt written response in order to continue our evaluation of your NDA.

Drug Process:

1) Please provide in-process control data in a spreadsheet file format such as .csv or .xls for the 90 mg dosage strength of Pre-Validation (X200 0915, X201 0915, and X202 0915) and Validation (1604V03, 1605V08, and 1605V09) batches used for the statistical evaluation of filling process capability.

If you have any questions, please contact me, at (240) 402-6153. Please respond by November 11, 2016.

Sincerely,

Rabiya Laiq, Pharm.D.
Regulatory Business Process Manager
Office of Program and Regulatory Operations
Office of Pharmaceutical Quality
Center for Drug Evaluation and Research

Rabiya Laiq -S

Digitally signed by Rabiya Laiq -S
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Date: 2016.11.07 14:27:27 -05'00'

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 207968

INFORMATION REQUEST

Novartis Pharmaceuticals Corporation
Attention: Haifeng Wu
Associate Director, Global Regulatory CMC
One Health Plaza, Building 339/01/1190
East Hanover, NJ 07936-1080

Dear Mr. Wu:

Please refer to your New Drug Application (NDA) submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Jadenu ® Sprinkle (deferasirox) granules 90mg, 180mg, and 360mg.

We also refer to your July 21, 2016 submission, containing your new drug application.

We are reviewing the Chemistry, Manufacturing, and Controls sections of your submission and have the following comments and information requests. We request a prompt written response in order to continue our evaluation of your NDA.

Drug Process:

1) Provide a summary of all in-process control data for your registration and pre-validation batches including the average and individual sachet weights and the variation of these values at each sample point taken during and after the packaging process.
2) We acknowledge that you have established in-process controls for the mean and individual fill weights of your drug product. These specifications are not adequate to ensure that your drug product complies with your assay specification (b) (4) as indicated by the failure to comply with your assay specification during stability studies. Tighten your in-process mean and individual weight controls to ensure that you comply with your assay specifications and statistically support these controls.
3) Provide and support a holding time of intermediates statement for the drug product manufacturing which establishes the complete manufacturing process time from raw material dispensing through packaging.

4) Provide all the batch records used to make and record registration and pre-validation batches.

5) Provide details of the specific equipment that was used in registration and pre-validation batches. Also provide details of the specific equipment that will be used for commercial batches including operating parameters with the ranges.

6) Provide descriptions and outcomes of any deviations or out of specifications for in-process tests during your registration and pre-validation batches. Describe and summarize any investigations which were performed in response to these occurrences.

7) Your IPC after end of production (offline) data is incomplete for lot X202 0915. The raw data is a 101 page document but only up to page 53 was provided as noted on page 436 of your x2020915 batch record. Provide the remainder of the (b) (4) (b) (4) document.

If you have any questions, please contact me, at (240) 402-6153. Please respond by October 21, 2016.

Sincerely,

Rabiya Laiq, Pharm.D.
Regulatory Business Process Manager
Office of Program and Regulatory Operations
Office of Pharmaceutical Quality
Center for Drug Evaluation and Research

Rabiya Laiq -S

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Date: 2016.10.04 17:04:52 -04'00'

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 207968

FILING COMMUNICATION –
NO FILING REVIEW ISSUES IDENTIFIED

Novartis Pharmaceuticals Corporation
Attention: Sara Lorie, MBA
Senior Associate Director, Drug Regulatory Affairs
One Health Plaza, Bldg. 337/B10-4A
East Hanover, NJ 07936-1080

Dear Ms. Lorie:

Please refer to your New Drug Application (NDA) dated July 21, 2016, received July 21, 2016, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA), for Jadenu Sprinkle (deferasirox) granules; 90, 180 and 360 mg.

We have completed our filing review and have determined that your application is sufficiently complete to permit a substantive review. Therefore, in accordance with 21 CFR 314.101(a), this application is considered filed 60 days after the date we received your application. The review classification for this application is Standard. Therefore, the user fee goal date is May 21, 2017.

We are reviewing your application according to the processes described in the Guidance for Review Staff and Industry: *Good Review Management Principles and Practices for PDUFA Products*. Therefore, we have established internal review timelines as described in the guidance, which includes the timeframes for FDA internal milestone meetings (e.g., filing, planning, mid-cycle, team and wrap-up meetings). Please be aware that the timelines described in the guidance are flexible and subject to change based on workload and other potential review issues (e.g., submission of amendments). We will inform you of any necessary information requests or status updates following the milestone meetings or at other times, as needed, during the process. If major deficiencies are not identified during the review, we plan to communicate proposed labeling and, if necessary, any postmarketing commitment requests by April 23, 2017.

At this time, we are notifying you that, we have not identified any potential review issues. Please note that our filing review is only a preliminary evaluation of the application and is not indicative of deficiencies that may be identified during our review.

PRESCRIBING INFORMATION

Your proposed prescribing information (PI) must conform to the content and format regulations found at 21 CFR 201.56(a) and (d) and 201.57. As you develop your proposed PI, we encourage you to review the labeling review resources on the *PLR Requirements for Prescribing Information* and *PLLR Requirements for Prescribing Information* websites including:

- The Final Rule (Physician Labeling Rule) on the content and format of the PI for human drug and biological products
- The Final Rule (Pregnancy and Lactation Labeling Rule) on the content and format of information in the PI on pregnancy, lactation, and females and males of reproductive potential
- Regulations and related guidance documents
- A sample tool illustrating the format for Highlights and Contents
- The Selected Requirements for Prescribing Information (SRPI) − a checklist of important format items from labeling regulations and guidances and
- FDA's established pharmacologic class (EPC) text phrases for inclusion in the Highlights Indications and Usage heading.

During our preliminary review of your submitted labeling, we have identified the following labeling issues and have the following labeling comments:

1. The Highlights section of the prescribing information is greater than ½ page in length. Submit a request to waive the requirements of 21 CFR 201.57(d)(8) regarding the length of Highlights of prescribing information. We will consider your request during labeling discussions.

At the end of labeling discussions, use the SRPI checklist to ensure that the PI conforms with format items in regulations and guidances.

PROMOTIONAL MATERIAL

You may request advisory comments on proposed introductory advertising and promotional labeling. Please submit, in triplicate, a detailed cover letter requesting advisory comments (list each proposed promotional piece in the cover letter along with the material type and material identification code, if applicable), the proposed promotional materials in draft or mock-up form with annotated references, and the proposed package insert (PI). Submit consumer-directed, professional-directed, and television advertisement materials separately and send each submission to:

OPDP Regulatory Project Manager
Food and Drug Administration
Center for Drug Evaluation and Research
Office of Prescription Drug Promotion (OPDP)
5901-B Ammendale Road
Beltsville, MD 20705-1266

Alternatively, you may submit a request for advisory comments electronically in eCTD format. For more information about submitting promotional materials in eCTD format, see the draft Guidance for Industry (available at: http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM443702.pdf).

Do not submit launch materials until you have received our proposed revisions to the package insert (PI), and you believe the labeling is close to the final version.

For more information regarding OPDP submissions, please see http://www.fda.gov/AboutFDA/CentersOffices/CDER/ucm090142.htm. If you have any questions, call OPDP at 301-796-1200.

REQUIRED PEDIATRIC ASSESSMENTS

Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), all applications for new active ingredients, new indications, new dosage forms, new dosing regimens, or new routes of administration are required to contain an assessment of the safety and effectiveness of the product for the claimed indication(s) in pediatric patients unless this requirement is waived, deferred, or inapplicable.

Because the drug for this indication has orphan drug designation, you are exempt from this requirement.

If you have any questions, call Suria Yesmin, Regulatory Project Manager, at (301) 348-1725.

Sincerely,

{See appended electronic signature page}

Ann T. Farrell, MD
Division Director
Division of Hematology Products
Office of Hematology and Oncology Products
Center for Drug Evaluation and Research

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/s/

SURIA YESMIN
09/30/2016

AMY C BAIRD
09/30/2016
Signing for Dr. Ann Farrell

From: Yesmin, Suria
To: Lorie, Sara
Cc: Yesmin, Suria; Baird, Amy
Subject: NDA 207968 Jadenu Sprinkle/IR/Due September 30
Date: Monday, September 26, 2016 2:27:03 PM

Dear Sara,

Regarding your NDA 207968, we have the following request for information. Please provide a response via e-mail by Friday, 09/30/16, followed by an official submission to the NDA.

Please send the contact information (PI name, address, phone and email address) for **all** clinical and analytical sites. Also, if it was submitted, please let us know where we can find this information in the application.

Thank you,
Suria

Suria Yesmin
Regulatory Project Manager
Division of Hematology Products (DHP)
FDA/CDER/OHOP
WO22, Room 3224
10903 New Hampshire Avenue
Silver Spring, MD 20993
Phone: 301-348-1725
E-Mail: Suria.Yesmin@fda.hhs.gov

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/s/

SURIA YESMIN
09/26/2016

Harris, Sarah

From: Lorie, Sara <sara.lorie@novartis.com>
Sent: Tuesday, September 13, 2016 3:44 PM
To: Harris, Sarah
Cc: Yesmin, Suria
Subject: RE: NDA 207968 Proprietary Name Resubmission

Sensitivity: Confidential

Categories: DHP

Hi Sarah,

Many thanks for your quick confirmation! We will proceed with submitting the revised PNR in this module.

Kind regards,
Sara

Sara Lorie, MBA
Senior Associate Director, Drug Regulatory Affairs-Oncology
Novartis Pharmaceuticals Corporation
One Health Plaza
East Hanover, NJ 07936-1080
USA

Phone +1 862 7787144
Fax +1 973 781 3310
sara.lorie@novartis.com

From: Harris, Sarah [mailto:Sarah.Harris@fda.hhs.gov]
Sent: Tuesday, September 13, 2016 3:42 PM
To: Lorie, Sara
Cc: Yesmin, Suria
Subject: RE: NDA 207968 Proprietary Name Resubmission
Sensitivity: Confidential

Hi Sara,
Yes, this is acceptable.

Thanks,
Sarah

From: Lorie, Sara [mailto:sara.lorie@novartis.com]
Sent: Tuesday, September 13, 2016 3:30 PM
To: Harris, Sarah
Cc: Yesmin, Suria
Subject: RE: NDA 207968 Proprietary Name Resubmission
Sensitivity: Confidential

Hi Sarah,

While compiling this submission, I was informed by our DRA Operations group that we do not currently have the capability to add files to M1.18, which becomes mandatory as of May 2017.

Can you please confirm it is acceptable to place this PNR in Module 1.12.4?

Thank you!

Kind regards,
Sara

Sara Lorie, MBA
Senior Associate Director, Drug Regulatory Affairs-Oncology
Novartis Pharmaceuticals Corporation
One Health Plaza
East Hanover, NJ 07936-1080
USA

Phone +1 862 7787144
Fax +1 973 781 3310
sara.lorie@novartis.com

From: Lorie, Sara
Sent: Tuesday, September 13, 2016 12:20 PM
To: 'Sarah.Harris@fda.hhs.gov'
Cc: 'Suria.Yesmin@fda.hhs.gov'
Subject: RE: NDA 207968 Proprietary Name Resubmission
Sensitivity: Confidential

Hi Sarah,

As an update, the PNR will be re-submitted in Module 1.18 this afternoon to the NDA (serial number 003). You should receive it within 24 hours.

For your reference, a copy of the submission cover letter is attached.

If you need anything else, please don't hesitate to let me know.

Kind regards,
Sara

Sara Lorie, MBA
Senior Associate Director, Drug Regulatory Affairs-Oncology
Novartis Pharmaceuticals Corporation
One Health Plaza
East Hanover, NJ 07936-1080
USA

Phone +1 862 7787144
Fax +1 973 781 3310
sara.lorie@novartis.com

From: Lorie, Sara
Sent: Tuesday, September 13, 2016 11:09 AM
To: Sarah.Harris@fda.hhs.gov
Cc: Suria.Yesmin@fda.hhs.gov
Subject: RE: NDA 207968 Proprietary Name Resubmission
Sensitivity: Confidential

Hi Sarah,

You are very welcome. I will keep you updated on the submission timing.

Kind regards,
Sara

Sara Lorie, MBA
Senior Associate Director, Drug Regulatory Affairs-Oncology
Novartis Pharmaceuticals Corporation
One Health Plaza
East Hanover, NJ 07936-1080
USA

Phone +1 862 7787144
Fax +1 973 781 3310
sara.lorie@novartis.com

From: Harris, Sarah [mailto:Sarah.Harris@fda.hhs.gov]
Sent: Tuesday, September 13, 2016 11:02 AM
To: Lorie, Sara
Cc: Yesmin, Suria
Subject: RE: NDA 207968 Proprietary Name Resubmission
Sensitivity: Confidential

Hi Sara,
Thank you for quickly confirming receipt of my email. We will look out for this submission at your earliest convenience.

Best,
Sarah

Sarah Harris, PharmD
Safety Regulatory Project Manager | Team Leader (Acting) | OSE | CDER | FDA
sarah.harris@fda.hhs.gov | 240.402.4774

From: Lorie, Sara [mailto:sara.lorie@novartis.com]
Sent: Tuesday, September 13, 2016 10:55 AM
To: Harris, Sarah
Cc: Yesmin, Suria
Subject: RE: NDA 207968 Proprietary Name Resubmission
Sensitivity: Confidential

Dear Sarah,

Thank you for your email. We will re-submit the PNR per your request.

Have a great day!

Kind regards,
Sara

Sara Lorie, MBA
Senior Associate Director, Drug Regulatory Affairs-Oncology
Novartis Pharmaceuticals Corporation
One Health Plaza
East Hanover, NJ 07936-1080
USA

Phone +1 862 7787144
Fax +1 973 781 3310
sara.lorie@novartis.com

From: Harris, Sarah [mailto:Sarah.Harris@fda.hhs.gov]
Sent: Tuesday, September 13, 2016 10:40 AM
To: Lorie, Sara
Cc: Yesmin, Suria
Subject: NDA 207968 Proprietary Name Resubmission
Sensitivity: Confidential

Dear Ms. Lorie,

Please refer to your recent new NDA submission for NDA-207968/SDN 1, dated 07/21/2016. Although a request for proprietary name review (PNR) was included in the submission, the document room failed to code the submission for PNR review.

Please submit a new "Request for Proprietary Name Review" for this application using the procedure below to ensure that the document room codes the submission accurately and opens an OSE PDUFA clock for the name review.

When submitting a proprietary name request for review to the Agency, it is crucial to include the statement "REQUEST FOR PROPRIETARY NAME REVIEW" in bold capital letters, at the top of your cover letter and on the first page of the main submission document (refer to the complete submission guidance link below).

If you require information on submitting requests for proprietary name review or PDUFA performance goals associated with proprietary name reviews, we refer you to the following:

- Guidance for Industry Contents of a Complete Submission for the Evaluation of Proprietary Names (http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM075068.pdf)

- PDUFA Reauthorization Performance Goals and Procedures Fiscal Years 2013 through 2017, (http://www.fda.gov/downloads/ForIndustry/UserFees/PrescriptionDrugUserFee/UCM270412.pdf)

Kind regards,
Sarah

Sarah Harris, PharmD
Safety Regulatory Project Manager | Team Leader (Acting) | OSE | CDER | FDA
sarah.harris@fda.hhs.gov | 240.402.4774

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/s/

SARAH J HARRIS
09/13/2016

From: Yesmin, Suria
To: Lorie, Sara
Cc: Yesmin, Suria
Subject: NDA 207968 Jadenu Sprinkle, Information Request
Date: Monday, August 22, 2016 8:59:02 AM

Dear Sara,

Regarding your new NDA 207968, we have the following request for information. Please provide a response via email by Friday, 08/26/16, followed by an official submission to the NDA.

"Provide the method validation reports or, if submitted earlier, identify the location of the reports for Studies F1102, F2104, F2105, F2106 and F2409."

Thank you,
Suria

Suria Yesmin
Regulatory Project Manager
Division of Hematology Products (DHP)
FDA/CDER/OHOP
WO22, Room 3224
10903 New Hampshire Avenue
Silver Spring, MD 20993
Phone: 301-348-1725
E-Mail: Suria.Yesmin@fda.hhs.gov

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/s/

SURIA YESMIN
08/22/2016

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 207968

INFORMATION REQUEST

Novartis Pharmaceuticals Corporation
Attention: Sara Lorie, MBA
Senior Associate Director, Drug Regulatory Affairs
One Health Plaza, Bldg. 337/B10-4A
East Hanover, New Jersey 07936-1080

Dear Ms. Lorie:

Please refer to your New Drug Application (NDA) submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for JADENU® (deferasirox) granules; 90, 180, and 360 mg.

We also refer to your July 21, 2016 submission, containing your new drug application.

We are reviewing the Chemistry, Manufacturing, and Controls sections of your submission and have the following comments and information requests. We request a prompt written response in order to continue our evaluation of your NDA.

Please update the 356h and Quality Module 3 with all Drug Substance, Drug Product and testing facilities. Each facility should be identified with a FEI number.

If you have any questions, please contact me, at (240) 402-6153. Please respond by August 12, 2016.

Sincerely,

Rabiya Laiq, Pharm.D.
Regulatory Business Process Manager
Office of Program and Regulatory Operations
Office of Pharmaceutical Quality
Center for Drug Evaluation and Research

Rabiya Laiq -S

Digitally signed by Rabiya Laiq -S
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, cn=Rabiya Laiq -S, 0.9.2342.19200300.100.1.1=2001555007
Date: 2016.08.08 13:21:17 -04'00'